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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/646, 763 10/24/00 LANQUETIN

M GEI-078

BIERMAN MUSERLIAN AND LUCAS  
600 THIRD AVENUE  
NEW YORK NY 10016

HM22/0403

EXAMINER

ART UNIT	PAPER NUMBER
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1617  
DATE MAILED:

04/03/01

**Please find below and/or attached an Office communication concerning this application or proceeding.****Commissioner of Patents and Trademarks**

<b>Offic Action Summary</b>	Application No.	Applicant(s)
	09/646,763	LANQUETIN ET AL.
	Examiner San-ming Hui	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Pri ority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- |   |   |
|---|---|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 20) <input type="checkbox"/> Other: _____ .                                   |

## DETAILED ACTION

### ***Specification***

A substitute specification including the claims for pages 1-32 and pages containing original claims 7 and 16 are required pursuant to 37 CFR 1.125(a) because there are holes punched through on the top of these pages so that disclosure and claims has been removed.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "suitable excipients" in claim 1, line 10 renders the claim indefinite since it is unclear what excipients are encompassed by the claim.

Materials recited in claim 1, line 5-6 and claim 6, line 2-3 are expressed in improper Markush language. The term "comprising" renders the claim indefinite because it is unclear what and how many additional agents or materials are included. See MPEP 2173.05(h).

Claim 8 contains the trademark/trade name Labrasol. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe one of the components of the solubilizing agent and, accordingly, the identification/description is indefinite.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saunal et al.(WO96/30000, English equivalent: USPN 6,010,716 is also provided) and Winters et al. (WO95/30409) in view of Eibl et al. (USPN 5,290,769), Merck Index (Budavari et al., editor, Merck Index, 12th ed., 1996: page889-890, Compound 5232), and Remington's Pharmaceutical Sciences (Gennaro et al., Remington's Pharmaceutical Sciences, 18th ed., 1990: page 1305).

Saunal et al. teaches a transdermal topical formulation of nomegestrol employing a solvent, absorption promoting agent, an active and a film-forming agent. Saunal et al. also teaches the solvent is ethanol or isopropanol (col. 7, line 13). The film-forming agent is hydroxypropylmethylcellulose. (col.3, line 58-59). The formulation of Saunal et al. also contains PVP VA, a polyvinylpyrrolidone derivatives(col. 3, line67).

Winters et al. teaches a topical formulation of 19-nor progesterone for systemic delivery of active. The formulation has a solvent such as alcohols (page 4, line 1-2), a film-forming agent such as methacrylates, and cellulose (page 4, line 8-11), a plasticizing agents such as Labrasol (page. 4, line 18), and a penetration enhancer.

The primary references do not expressly teach the use of propylene glycol, isopropylidene glycerol, isopropylideneglycerol, anionic copolymer of methacrylic acid and ethyl acrylate, and carbomer as carrier materials. The references do not expressly teach the use of a gelling agents in the composition.

However, Eibl et al. teaches the use of propylene glycol and copolymer of methacrylic acid and ethyl acrylate as pharmaceutical auxiliary agents in topical formulations (see col 5, line 66 and col. 6, line 19-20).

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The Merck Index teaches that isopropylideneglycerol can be used as a solubilizing or plasticizing agent in pharmaceutical compositions. See page 889-890, Compound 5232)

Remington's Pharmaceutical Sciences teaches that carbomer is useful as a gelling and emulsifying agent in pharmaceutical compositions. (See page 1305, col. 1)

Therefore it would have been obvious for one of ordinary skill in the art at the time the invention was made to formulate nomegestrol into a topical formulation with a gelling agent and other carrier materials herein.

The employment of nomegestrol as an active agent in a topical pharmaceutical composition with carrier materials herein is motivated because these carrier materials are known pharmaceutical excipients. The incorporation of active agents in compositions with known carrier materials is considered within the skill of artisan.

The optimization of result effect parameters (e.g., amounts of ingredients) is obvious as being within the skill of the artisan.

The instant composition containing a 19-nor-progesterone derivative would be reasonably expected to be similarly useful to raise progesterone levels in a host without regard to their status as being menopausal or premenopausal.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Monday to Friday from 8:30 to 5:00.

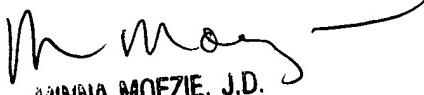
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui  
March 26, 2001



MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600